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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,770	01/08/2002	Yi Hu	LEX-0294-USA	3157

7590 02/05/2003

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EXAMINER
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SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/05/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/041,770

Applicant(s)

HU ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

Applicant's response, on November 20, 2002, Paper No. 7, to the first Office Action on the Merits of this case is acknowledged. It is acknowledged that applicants have amended Claims 1, 2, and 4 and added new Claims 5 and 6. Claims 1-4 are hereby reconsidered and new Claims 5 and 6 are considered.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a well established utility for either the nucleic acid molecule of SEQ ID NO: 1, any nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2, or the polypeptide of SEQ ID NO: 2. Furthermore, the claimed invention is not supported by an asserted utility based on either a demonstrated function for the protein of SEQ ID NO: 2, or by a deduced function for said protein supported by homology to known proteins. The reasons for rejection are further described in the prior action.

Applicants argue that the present invention has a number of substantial and credible utilities. For example, as a specific marker for the human genome, in assessing gene expression patterns using high-throughput DNA chips, localizing the specific region of human chromosome 1 that contains the gene encoding the given polynucleotide, in defining how the encoded exons are spliced together to produce an active transcript, and in expanding the utility of the data coming from the human genome project. While applicant argue that the polynucleotide of SEQ

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ID NO: 1 can be used as a specific marker for the human genome, an extremely large number of markers for human DNA already exist. Applicants have not identified any particular reason for the use of SEQ ID NO: 1 as a marker for human DNA or any particular benefit that would derive from DNA analysis with this particular polynucleotide. Applicants have also not identified any particular reason for use of this particular polynucleotide to analyze gene expression patterns using "DNA chips". Likewise, applicants have not identified any particular reason for localizing the specific region of the chromosome containing the coding sequences of this polynucleotide or in defining how the coding regions are spliced into an active transcript. The specific reasons why SEQ ID NO: 1 expands the utility of the data coming from the human genome project is not identified. Each of these utilities is an application which would apply to every member of a general class of materials and/or is a use only for further research to determine a use for SEQ ID NO: 1 or the protein encoded thereby. As such, these asserted utilities are not specific (for those applicable to all human DNAs) or not substantial because the use of SEQ ID NO: 1 therein is only potential and not in currently available in practical form. Therefore, rejection of Claims 1-4 under 35 U.S.C. 101 is maintained because the claimed invention is not supported by credible asserted utility or an established utility. Since new Claim 5 and 6 recite vectors and host cells comprising SEQ ID NO: 1 and/or nucleic acids encoding SEQ ID NO: 2, Claims 5 and 6 are also rejected under 35 U.S.C. 101 for the reason described above.

***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph. Since, the claimed invention is not supported by either a demonstrated, deduced, or well established function for the protein of SEQ ID NO: 2, the polynucleotide set forth by SEQ ID NO: 1, or any polynucleotide encoding the protein of SEQ ID NO: 2, for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Claims 5 and 6 are also rejected under 35 U.S.C. 112, first paragraph for the same reasons.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 8:30-5 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP ~~1000~~  
/bds